October 2004

Montana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 200513, 301 S Park Ave, 4th Floor
Helena, MT 59620-0513

ISMP Seeks Epinephrine/Ephedrine Label Changes

Spurred by the recent death of a 16-year-old patient in a hospital emergency department, the Institute for Safe Medication Practices (ISMP) is urging the elimination of ratio expressions for epinephrine injection and labeling changes to reduce confusion between epinephrine and ephedrine. ISMP has petitioned the United States Pharmacopeia (USP), stressing that epinephrine should be expressed only in mg per mL, except when being combined with local anesthetics.

"Factors that contribute to epinephrine dosing errors include lack of understanding of the difference between dose concentrations (for instance, 1:1,000 or 1 mg/mL and 1:10,000 or 0.1 mg/mL) and the fact that it is easy to confuse the number of zeros in the ratio, especially when expressed without the commas," ISMP says. "There also is no warning on ampuls of epinephrine reminding practitioners that the more concentrated forms need to be diluted before use."

Fact or Fiction, Truth or Dare?

Which of the following statements are true?

- A C-II prescription must be presented for filling within seven days of being written.
- A C-V prescription may not be refilled more than five times or longer than six months.
- Partial filling of a C-II prescription renders the remainder of the prescription void.
- Emergency phone-in of C-II prescriptions must be followed up with a hard copy prescription within 72 hours.
- A C-II prescription becomes void 60 days after the date it was written.
- Multiple C-II prescriptions may be written for the same patient, for the same drug, on the same day if the prescriber postdates the prescriptions.
- Prescriptions for controlled substances may not be written on the same blank as other prescriptions.

If you answered "none of the above," pat yourself on the back and take the afternoon off! *Nothing* **in federal or Montana law or rule mandates that a C-II prescription be filled within a certain amount of time.** Some states do specify a time limit, but Montana does not. C-III and C-IV prescriptions expire six months after the date on which they were written, but **expiration of C-II prescriptions** is ***not*** addressed. As a pharmacist, you are expected to exercise professional judgment in filling all prescriptions, including C-IIs. Most pharmacists would view a 30-day-old emergency room prescription for 30 Percocet® differently than a similar 30-day-old prescription written by a patient's oncologist for breakthrough pain. Pharmacists can refuse to fill prescriptions for many valid reasons; however, in Montana the age of a C-II prescription is **not** a valid reason in and of itself to refuse filling.

Despite frequent assertions to the contrary, C-Vs are **not** subject to the "5 refills or 6 months, whichever comes first" limitation of C-III and C-IV prescriptions. Honestly.

Partial filling of a C-II either because your stock is running low or the patient cannot afford the entire prescription will void the balance of the prescription if it is not filled and picked up within **72 hours**. Partial filling of C-IIs for up to 60 days **is** allowed for patients in long-term care if necessary.

An emergency phoned-in C-II prescription (for an amount necessary to cover the emergency) must be followed up with a hard copy prescription within **seven days**, not 72 hours. The previous 72-hour window was wisely extended to seven days.

Postdating on **any** prescription is not allowed, and certainly not on C-IIs. A prescription is a legal document, and dating it with an incorrect date is not correct.

Prescriptions should always be dated with the date on which they were written. The prescriber should add "Do not fill before _____" on subsequent prescriptions.

Some states limit the numbers and types of prescription orders that can be placed on one blank, but Montana is not among them. If you feel there is a need for some sort of limitation (I have seen terrible examples over the years) let the Board of Pharmacy know. However, keep in mind that the burden would fall upon you as a pharmacist to deal with incorrectly written prescriptions – most likely at the time of day when a roadblock is needed least.

Welcome Mark Meredith, Our New Board Member!

Mark Meredith has replaced Tony Fisher as the Board's institutional pharmacist member. Born in Missoula, Mark was raised and educated in Anaconda. Mark graduated with a bachelor of science in pharmacy degree in 1997 and began work as a pharmacist at Wal-Mart in Helena. While there, he continued his studies and earned his PharmD degree in 1999. Now, Mark serves as clinical coordinator at St Peter's Hospital in Helena. He brings a wide range of experience to the Board, including retail, hospital, and home infusion. He welcomes the challenges the Board faces with open arms, saying, "The practice of pharmacy in Montana is predominately rural, which poses some interesting challenges compared to more urban areas. I look forward to serving the Board to the best of my abilities. Hopefully, we can make some positive changes to the practice of pharmacy and really progress as a state." In his free time, Mark enjoys spending time with his wife, Regan, and two Labrador Retrievers, Bailey and Gauge. He also enjoys many outdoor activities.

The Board welcomes Mark, and would like to thank Tony Fisher once again for his passion and dedication to quality health care and the practice of pharmacy. His term on the Board was all too short, but his vision for pharmacy and his mark on pharmacy practice in Montana will remain well into the future. The Board, its staff, and the pharmacists of Montana join in thanking Tony for serving us so well.

JCAHO's Compliance Expectations for USP 797

By Bob Sobolik, performance and safety improvement specialist, McKesson Medication Management

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National Pharmacy Compliance News

(Applicability of the contents of articles in the National Pharmacy Compliance News to a particular state or jurisdiction should not be assumed and can only be ascertained by examining the law of such state or jurisdiction.)

New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose,
- 20 mg or more of calcium in a single dose,
- 8 mg or more of magnesium in a single dose, or
- 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium,
- more than 3.2 grams calcium,
- more than 600 mg magnesium, or
- more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlafaxine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

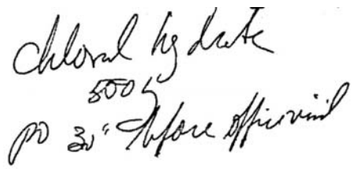
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as "30 cc before office visit" and instructed the mother to give her child that amount. In truth, the physician wanted the child to receive 500 mg 30 *minutes* before the office visit. The double hash-mark symbol ("), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.



Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as "give chloral hydrate 5 cc prn sedation" or ". . . prn agitation," rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, "5 mL," "one teaspoonful," etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product's boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy's current "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (*Pediatrics* 2002; 110:836-838) recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children's sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP's Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate's ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/698-6227 or visit the Association's Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE™, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

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The materials below are the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) expectations for compliance with the new sterile products compounding standard from USP. Complete standards are available from USP and the sterile compounding portion only is available from the American Society of Health-System Pharmacists. JCAHO expects compliance for all types they surveyed including Acute Care, Critical Access, Home Care, and Behavioral Health Care. Listed below is a synopsis of the highlights from the ISMP teleconference "Turning a New Chapter (797) On IV Drug Compounding Safety," July 15, 2004, with speakers Larry Trissel and Darryl Rich. Conference cassette tapes are available from ISMP.

JCAHO Expected Compliance Date: Current

- *General:* Cleaning and sanitizing work spaces; Aseptic technique; Proper scrubbing
- *Quality Control (QC) Practices:* Review of orders and packages of ingredients to assure correct identity and amounts of ingredients; Visual inspection of compounded sterile products (CSP)
- *Finished Product-Release Checks and Tests:* Physical inspections; Compounding accuracy checks; High-risk level products; Sterility, pyrogen, potency testing
- *Maintaining Product Quality and Control Once the CSP Leaves the Pharmacy:* Administration
- *Other Issues:* Patient education (home care); Patient monitoring; Adverse reaction reporting; Complaint procedures; Periodic review of quality control documents

JCAHO Expected Compliance Date: January 1, 2005

- Conduct a risk assessment (or Gap Analysis) of compliance to all provisions of the chapter
- Develop an action plan for each section of the chapter with specific time frames for compliance *approved by leadership.*
- *Personnel Performing Compounding*
  Training and instruction: Theoretical principles; Practical skills
  Competence assessment: Passing written test; Media fill testing, per risk level
- *Environment Design of Drug Preparation Rooms:* Renovation plan
- *Verification of Environmental Control:* Certification of laminar airflow workbenches and barrier isolates every six months; Certification of the buffer room/zone and anteroom/zone every six months
- *Storage and Labeling:* Specific labeling requirements; Specific beyond-use dating policies, procedures, and requirements

JCAHO Expected Compliance Date: July 1, 2005

- *Formal Quality Assurance (QA) Plan:* Formalized in writing; Describes specific monitoring and evaluation activities (measures identified)
- *Environment Design of Drug Preparation Rooms:* Interim measures
- *General*: Standard operating procedures; Proper attire
- *QC Practices:* Visual confirmation of personnel processes regarding gowning, etc
- *Storage and Labeling:* Policies regarding storage
- *Finished Product-Release Checks and Tests:* Policies and procedures
- *Equipment Used in Compounding:* Calibration; Routine maintenance; Personnel training
- *Maintaining Product Quality and Control Once the CSP Leaves the Pharmacy:* Packaging, handling, and transport; Use and storage; Personnel training
- *Other Issues:* Re-dispensing compounded sterile drugs

JCAHO Expected Compliance Date: January 1, 2006

- *Formal QA Plan:* Reporting and evaluation of data; Identification of follow-up activities; Delineation of individual responsibilities
- *Verification of Environmental Control:* Bacterial monitoring using an appropriate manner at least monthly

JCAHO Expected Compliance Date: January 1, 2008

- *Environment Design of Drug Preparation Rooms:* Completion date

Unresolved Issues

The following issues will be addressed in October 2004: Beyond-use date of seven days for refrigerated medium-risk products in home care; Use of shoe covers; Use of sterile Isopropyl Alcohol; and Dating of multi-dose vials.

Survey Priorities Through the End of 2004

Development and implementation of the action plan; Personnel training and evaluation (ie, competence assessment); Beyond-use dating and labeling; Verification of automated compounding devices; Finished preparation release checks and tests; Aseptic technique.

JCAHO Expectations July 1, 2004 to December 31, 2004

- For provisions of Chapter 797 that are identical to JCAHO standards, compliance will be evaluated and scored.
- Should have begun the process of compliance evaluation and formulated an initial action plan.

Other areas of Chapter 797 will be evaluated but ***not*** scored. Consultation will be provided.

The *Montana Board of Pharmacy News* is published by the Montana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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